

§ 101.65

21 CFR Ch. I (4–1–11 Edition)

immediate proximity to the claim that is printed in the largest type; and

(D) As required in §101.13(j)(2) for relative claims:

(1) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than _____); and

(2) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces (e.g., “Cholesterol lowered from 30 mg to 22 mg per 3 oz of product.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (d)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for “low cholesterol.”

(e) “*Lean*” and “*extra lean*” claims. (1) The term “lean” may be used on the label or in labeling of foods except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in labeling of a mixed dish not measurable with a cup as defined in §101.12(b) in table 2, provided that the food contains less than 8 g total fat, 3.5 g or less saturated fat and less than 80 mg cholesterol per reference amount customarily consumed;

(3) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) or main dish products as defined in §101.13(m) provided that the food contains less than 10 g total fat, 4.5 g or less satu-

rated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(4) The term “extra lean” may be used on the label or in the labeling of foods except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(5) The term defined in paragraph (e)(4) of this section may be used on the label or in labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

(f) *Misbranding*. Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, 17343, Apr. 2, 1993, as amended at 58 FR 44032, Aug. 18, 1993; 58 FR 60105, Nov. 15, 1993; 59 FR 394, Jan. 4, 1994; 60 FR 17207, Apr. 5, 1995; 61 FR 59001, Nov. 20, 1996; 63 FR 26980, May 15, 1998; 72 FR 1459, Jan. 12, 2007]

§ 101.65 Implied nutrient content claims and related label statements.

(a) *General requirements*. An implied nutrient content claim can only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms described in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §101.13; and

(3) The food for which the claim is made is labeled in accordance with §101.9, §101.10, or §101.36, as applicable.

(b) *Label statements that are not implied claims*. Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under §101.13(b)(2). The following types

of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section:

(1) A claim that a specific ingredient or food component is absent from a product, provided that the purpose of such claim is to facilitate avoidance of the substances because of food allergies (see § 105.62 of this chapter), food intolerance, religious beliefs, or dietary practices such as vegetarianism or other nonnutrition related reason, e.g., “100 percent milk free;”

(2) A claim about a substance that is nonnutritive or that does not have a nutritive function, e.g., “contains no preservatives,” “no artificial colors;”

(3) A claim about the presence of an ingredient that is perceived to add value to the product, e.g., “made with real butter,” “made with whole fruit,” or “contains honey,” except that claims about the presence of ingredients other than vitamins or minerals or that are represented as a source of vitamins and minerals are not allowed on labels or in labeling of dietary supplements of vitamins and minerals that are not in conventional food form.

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., “corn oil,” “oat bran,” “dietary supplement of vitamin C 60 mg tablet”).

(5) A statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient benefit (e.g., “corn oil margarine,” “oat bran muffins,” or “whole wheat bagels”), unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount; and

(6) A label statement made in compliance with a specific provision of part 105 of this chapter, solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part.

(c) *Particular implied nutrient content claims.* (1) Claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g.,

“high in oat bran”) are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases “contains the same amount of [nutrient] as a [food]” and “as much [nutrient] as a [food]” may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a “good source” of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., “as much fiber as an apple,” “Contains the same amount of Vitamin C as an 8 oz glass of orange juice.”).

(3) Claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either “low” in or a “good source” of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., “high in _____”), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

(d) *General nutritional claims.* (1) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and

(ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).

(2) You may use the term “healthy” or related terms (e.g., “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

§ 101.65

21 CFR Ch. I (4–1–11 Edition)

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables ¹	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams (g) total fat per RA ² and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 mg cholesterol per RA and per 100 g	At least 10 percent of the RDI ³ or the DRV ⁴ per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber
(E) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	Low fat as defined in § 101.62(b)(3)	Low saturated fat as defined in § 101.62(c)(3)	90 mg or less cholesterol per LS ⁵	At least 10 percent of the RDI or DRV per LS of two nutrients (for a main dish product) or of three nutrients (for a meal product) of: vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

¹ May include ingredients whose addition does not change the nutrient profile of the fruit or vegetable.

² RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).

³ RDI means Reference Daily Intake (§ 101.9(c)(8)(iv)).

⁴ DRV means Daily Reference Value (§ 101.9(c)(9)).

⁵ LS means Labeled Serving, i.e., the serving size that is specified in the nutrition information on the product label (§ 101.9(b)).

(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be...
(A) A food with a RA that is greater than 30 g or 2 tablespoons (tbsp.)	480 mg or less sodium per RA and per LS
(B) A food with a RA that is equal to or less than 30 g or 2 tbsp.	480 mg or less sodium per 50 g ¹

If the food is...	The sodium level must be...
(C) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	600 mg or less sodium per LS

¹ For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts per RA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the "prepared" form of the product.

(iii) The food complies with the definition and declaration requirements in this part 101 for any specific nutrient content claim on the label or in labeling, and

(iv) If you add a nutrient to the food specified in paragraphs (d)(2)(i)(D), (d)(2)(i)(E), or (d)(2)(i)(F) of this section to meet the 10 percent requirement, that addition must be in accordance with the fortification policy for foods in § 104.20 of this chapter.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 24249, May 10, 1994; 59 FR 50828, Oct. 6, 1994; 62 FR 49858, Sept. 23, 1997; 63 FR 14355, Mar. 25, 1998; 70 FR 56848, Sept. 29, 2005]

§ 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a; and

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of

the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference (e.g., if appropriate, “not recommended for baking purposes”). Such statement shall comply with the requirements of § 101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement “*Ingredients not in regular butter” shall immediately follow the ingredient statement in the same type size.

[58 FR 2455, Jan. 6, 1993]

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not exempted under section 403(r)(5)(A) through (r)(5)(C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are: